STAY AWAKE- caffeine 200 mg tablets tablet
Spirit Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Stay Awake (CAFFEINE 200 MG)

Drug Facts

Active ingredient (in each tablet)
Caffeine 200 mg

Purpose

Alertness Aid

Use

■ helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

Warnings

For occasional use only

Do not use

■ in children under 12 years of age
■ as a substitute for sleep

When using this product limit the use of caffeine containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

Stop use and ask a doctor if fatigue or drowsiness persists or continues to recur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.1(800)222-1222

Directions

■ adults and children 12 years of age and over: take 1 tablet not more often than every 3 to 4 hours.

Other information

■ store at room temperature
■ avoid excessive heat (greater than 100°F) or humidity

carnauba wax*,croscarmellose sodium, colloidal silicon dioxide*, dextrates*, D&C yellow #10 aluminum lake, dicalcium phosphate*, FD&C red#40 lake*, FD&C yellow #6 aluminum lake*, hypromellose, lactose*, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide*, titanium dioxide
*contains one or more of these ingredients

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Stay Awake

Caffeine 200 mg - alertness aid

safe and effective

20 Tablets

STAY AWAKE
caffeine 200 mg tablets tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-4151
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
DEXTRATES (UNII: G263MI44RU)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	1mm
Flavor		**Imprint Code**	ET38;AZ076;TCL343
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4151-2	1 in 1 CARTON	04/29/2021	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part340	04/29/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 11/2021 Spirit Pharmaceuticals LLC